

## REMARKS/ARGUMENTS

The non-final Office Action of January 2, 2008, has been carefully reviewed and these remarks are responsive thereto. Claims 1-28 were pending and stand rejected. By this response, claims 1, 3, 5, 11, 21, 22, 24, 27 and 28 have been amended, claims 4, 7, 8, 12, 16, 20 and 26 have been canceled and new claim 29 has been added. No new matter has been added to the application.

### *New Claims*

New claim 29 has been added and recites the following:

29. A delivery system for pharmaceutical agents wherein said system comprises liposomes which comprise in their internal compartment a pharmaceutical agent and which have linked to their external surface the cell adhesion molecule NCAM or a fragment thereof, wherein said delivery system comprises DNA that encodes the human dystrophin protein.

Claim 29 is supported at least by page 4, lines 17-18, therefore no new matter has been added.

### *Information Disclosure Statement*

The Information Disclosure Statement filed 1/10/2005 included a reference, DE 100 56 136 with no English translation. The English translation of the abstract of DE 100 56 136 is being filed in conjunction with this response.

### *Claim Rejections Under 35 U.S.C. §175(c)*

Claims 4-28 were objected to under 36 CFR 1.75(c) as being improper form because a multiple dependent claim cannot serve as a basis for any other multiple dependent claims, either directly or indirectly. In the instant case, the multiple dependent claims 4-28 directly or indirectly depend from the multiple dependent claim 2. It is believed that the rejection was intended to refer to multiple dependent claim 3, because claim 3 as filed was a multiple dependent claim whereas claim 2 was not. In response, claim 3 has been amended to depend only from claim 1.

Additionally, claims 26-28 were rejected due to being in improper form because they do not refer to the other claims in the alternative only. Claim 26 has been canceled, rendering the rejection moot with respect to claim 26. By this response, claim 27 has been amended to depend from claim 1, and claim 28 has been amended to recite, in part, “according to any one of claims...” to refer to the other claims in the alternative only. The Office Action stated that claims 4-28 were withdrawn from examination and were not further treated on the merits. The Applicant respectfully requests that claims 1-3, 5-6, 9-11, 13-15, 17-19, 21-25 and 27-29 to be considered on the merits.

***Claim Rejections Under 35 U.S.C. §103(a)***

Claims 1-3 were rejected under 35 U.S.C. 103(a), as being unpatentable over Poulsen et al (2005/0037445), in view of each Maurer et al. (Expert Opinion), Ranheim et al. (Proc. Natl. Acad. Sci), and Schreier et al. (J. Biological Chemistry). The Applicant respectfully traverses the rejection. Claim 1 has been amended to specify that the pharmaceutical agent is DNA and that the delivery system comprises a DNA integrase activity or a molecule encoding such a DNA integrase activity. Amended claim 1 is supported at least by page 3, lines 6-7 and page 3, line 34 through page 4, line 13 of the application as originally filed. Amended independent claim 1 now recites the following:

1. A delivery system for pharmaceutical agents wherein said system comprises liposomes which comprise in their internal compartment a pharmaceutical agent and which have linked to their external surface the cell adhesion molecule NCAM or a fragment thereof, wherein said pharmaceutical agent is DNA and said delivery system comprises a DNA integrase activity or a molecule encoding such a DNA integrase activity.

Poulsen discloses targeting complexes that are capable of being internalized into cells. The targeting complexes include at least one binding partner to associate with a cell surface molecule, and a bioreactive species. (See paragraphs [0079] and [0087] of Poulsen) As recognized by the Examiner, Poulsen does not specifically teach liposomes comprising DNA as a bridge between a nucleic acid and a targeting moiety. In other words, Poulsen does not teach

liposomes comprising DNA in their internal compartment and having the cell adhesion molecule NCAM or a fragment thereof. Further, Poulsen is silent regarding targeting complexes that comprise "a DNA integrase activity or a molecule encoding such a DNA integrase activity" as claimed in amended claim 1.

None of Maurer, Ranheim nor Shreier remedy the deficiencies of Poulsen with respect to liposomes comprising DNA integrase activity. Maurer is directed to a review of liposomes for drug delivery and discusses only conventional drugs, DNA and pDNA (See Abstract and page 936, column 1 through page 941, column 1 of Maurer). Maurer is thus completely silent regarding DNA integrase activity. Ranheim is directed to the interaction of neural cell adhesion molecules (NCAM) on two different cells and is totally unrelated to DNA integrase activity (See Abstract of Ranheim). Shreier is directed to glycosylphosphatidylinositol-anchored proteins for use as targeting molecules for liposomes, and is entirely silent regarding DNA integrase activity (See Abstract of Shreier). Consequently, it would not have been obvious for one of skill in the art to develop the invention of amended claim 1 merely from the disclosures of Poulsen, Maurer, Ranheim and Shreier. Amended claim 1 is therefore patentable over Poulsen in view of Maurer, Ranheim and Shreier. Claims 2 and 3 depend from claim 1 and are patentable for at least the same reasons as amended claim 1 and for the additional features recited therein.

Claims 1 and 2 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Murphy (U.S. Patent No. 6,635,476), in view of Poulsen et al. and Ranheim et al. As discussed above, claim 1 has been amended to include the features that "said pharmaceutical agent is DNA and said delivery system comprises a DNA integrase activity or a molecule encoding such a DNA integrase activity." Murphy is directed to targeted vectors "that are complexed to a targeting moiety by coordinate covalent linkages mediated by a transition metal ion" (Abstract of Murphy). Poulsen and Ranheim are discussed above as lacking disclosure related to liposomes comprising DNA integrase activity, and Murphy is also silent regarding DNA integrase activity. Accordingly, amended claim 1 is patentable over Murphy in view of Poulsen and Ranheim. Claim 2 depends from claim 1 and is patentable for at least the same reasons as amended claim 1

Appln. No.: 10/520,909  
Amendment dated June 30, 2008  
Reply to Office Action of January 2, 2008

and for the additional features recited therein. The Applicant respectfully requests withdrawal of the 35 U.S.C. § 103(a) rejections.

### CONCLUSION

All rejections having been addressed, the Applicant respectfully submits that the instant application is in condition for allowance, and respectfully requests prompt notification of the same. If there are any questions, the examiner is invited to contact Applicants' undersigned representative at the number noted below.

Respectfully submitted,  
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Dated: June 30, 2008

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